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A Definition of “Flare” in Low Back Pain: A Multiphase Process Involving Perspectives of Individuals With Low Back Pain and Expert Consensus

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Abstract: Low back pain (LBP) varies over time. Consumers, clinicians, and researchers use various terms to describe LBP fluctuations, such as episodes, recurrences and flares. Although "flare" is used commonly, there is no consensus on how it is defined. This study aimed to obtain consensus for a LBP flare definition using a mixed-method approach. Step 1 involved the derivation of a preliminary candidate flare definition based on thematic analysis of views of 130 consumers in consultation with an expert consumer writer. In step 2, a workshop was conducted to incorporate perspectives of 19 LBP experts into the preliminary flare definition, which resulted in 2 alternative LBP flare definitions. Step 3 refined the definition using a 2-round Delphi consensus with 50 experts in musculoskeletal conditions. The definition favored by experts was further tested with 16 individuals with LBP in step 4, using the definition in three scenarios. This multiphase study produced a definition of LBP flare that distinguishes it from other LBP fluctuations, represents consumers' views, involves expert consensus, and is understandable by consumers in clinical and research contexts: "A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to tolerate and generally impacts your usual activities and/or emotions."

Perspective: A multiphase process, incorporating consumers' views and expert consensus, produced a definition of LBP flare that distinguishes it from other LBP fluctuations.

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Key words: Low back pain, flare, flare-up, definition, consensus.

Low back pain (LBP) is the most burdensome musculoskeletal condition worldwide,⁷ affects all ages,¹⁷ and contributes to inequality globally.² Most individuals experience LBP at least once and for many, LBP is a lifelong problem with trajectories marked by fluctuations.^{1,14,15,18,27} Terms such as *acute*, *subacute*, and *chronic* provide little or no information regarding symptom variation, and do not discriminate between chronic LBP and multiple acute periods. The terms *episode*,^{10,12,29} *recurrence*,^{12,23} and *flare*^{22,26,30} are used to describe fluctuations, and may characterize LBP trajectories, but it is unclear how they are defined and differ. *Episodes* and *recurrences* are defined as specific fluctuations preceded by a symptom-free period.^{12,23,24} However, not all fluctuations meet this criterion. Although most experience LBP variation (short/long term¹⁴), not all fluctuations are considered important by individuals.²²

The determination of which variations are important remains an issue. Many with LBP and other musculoskeletal conditions describe "flare/flare up" as a distinct type of symptom fluctuation.^{16,19,21,28} Flares are not necessarily preceded by a symptom-free period and commonly represent transient worsening.^{22,26,30} An important distinction from other fluctuations is that individuals indicate flare involves domains other than pain. A systematic review of flare definitions in musculoskeletal conditions suggested it cannot be reduced to consideration of pain, but is a multifaceted experience marked by features such as impact on function and emotions.⁹ Individuals with LBP support this notion.²² Further, workers consider flares to involve activity limitations, participation restrictions, fear of symptom worsening, and the need for help to manage symptoms.³⁰ Flares are a burdensome aspect of LBP.^{3,8,30} They disrupt work ability and increase disability and work absenteeism.^{25,26} Notably, consideration of flares differs between individuals with LBP and clinicians. Whereas clinicians focus on clinical signs, patients have a broader biopsychosocial view.^{9,11} Flares are likely to be an important

event that may characterize the impact of some LBP trajectories. However, without a consistent definition of a LBP flare, it is not possible to compare data from individuals with pain, clinicians, and researchers, or to pool data from different sources.

A clear definition of a LBP flare is necessary, yet there is no consensus regarding what it should include. LBP flare was initially described as "a phase of pain superimposed on a recurrent or chronic course...a period (usually a week or less) when back pain is markedly more severe than is usual...must meet criteria for recurrent or chronic pain, and be able to identify the beginning (and the end if the flare-up has resolved) of a period when back pain was substantially more intense than usually experienced."²⁹ This definition was applied to people with recurrent/chronic LBP, and adapted to acute LBP.²⁵ The definition's foundation is unclear, and it does not align with the multidimensionality expressed by individuals with LBP.

This study aimed to develop a definition for LBP flare that distinguishes it from other fluctuations. The study involved multiple steps that considered perspectives from experts and individuals with LBP to achieve a definition for research and clinical practice.

Methods

This mixed methods study to derive a definition of LBP flare comprised 4 steps: 1) derivation of LBP flare definition from perspectives of individuals with LBP; 2) incorporation of experts' perspectives in a preliminary LBP flare definition at the International Forum for Back and Neck Pain Research in Primary Care (Buxton UK, June 2016); 3) a Delphi process with experts to refine the definition and reach consensus expert opinion; and 4) qualitative testing of the definition with individuals with LBP. Ethical approval was obtained from the Human Research Ethics Committee of the University of Queensland (2017000183; 2015001094).

Step 1: Derivation of LBP Flare Definition From Qualitative Research on Consumers' Perspectives

A definition of flare was proposed on the basis of findings of mixed methods online survey research conducted with 130 individuals who had previous experience with LBP.²² In that study, individuals with LBP completed an online survey in which they answered questions regarding their experiences and understanding of LBP flares. Survey results were analyzed using thematic analysis, content analysis, and descriptive statistics. That study provided information of the consumer conceptualization of flare. In the current study, those data were used to derive a draft definition of flare. Five authors (P.H., N.C., J.S., M.F., J.M.) met on 3 occasions to discuss the survey results, consider consumers' perspectives, and discuss terminology to reflect the features that distinguish flare from other symptom fluctuations. The initial proposed definition was refined in consultation with an expert consumer writer (T.D.).

Step 2: Incorporation of Experts' Perspectives in Preliminary LBP Flare Definition

A workshop was held at the International Forum for Back and Neck Pain Research in Primary Care (Buxton UK, June 2016) with a group of 19 experts in LBP. After a brief introduction to the topic, the candidate definition of LBP flare derived from step 1 was presented. This step aimed to integrate the perspectives of experts into the candidate flare definition. The meaning of the definition as a whole, and the specific selection of words, were discussed. At the end of the workshop, participants were invited to contribute to step 3. After the workshop, 4 authors met (P.H., N.C., J.S., M.F.) to discuss modifications to the definition based on the workshop discussions and notes made during the workshop by P.H., N.C., and M.F. Four candidate definitions were developed with slight variation in wording, and then refined to 2 that reduced the definition to single sentences and to improve wording based on consultation with the consumer writer.

Step 3: Delphi Process to Refine Definition and Reach Consensus Expert Opinion

A 2-round Delphi process¹³ was conducted to 1) obtain feedback from a diverse group of international experts regarding the 2 proposed definitions for flare, and 2) re-present a refined definition (based on feedback from round 1) to the participants to evaluate its acceptability. The Delphi process was implemented online via a web-based system (Google Drive). Sixty-two experts were invited to participate in the Delphi process. Contributors were to meet ≥ 2 of the following criteria: ≥ 5 papers in the previous 3 years related to musculoskeletal pain; invitation to present keynote lecture at international conference related to musculoskeletal pain; or

contribution to clinical practice guideline or major systematic review in musculoskeletal pain). The panel included representation from the following professions: physiotherapy (n = 23), rheumatology (n = 6), epidemiology (n = 4), chiropractic (n = 4), primary care (n = 3), medicine (other) (n = 3), orthopedic surgery (n = 2), physiatry (n = 1), psychology (n = 1), occupational therapy (n = 1), and medical science (n = 1). A patient advocate was also included in this Delphi process.

Round 1

In round 1, the 2 revised versions of the preliminary flare definition (step 2) were presented to the panel. Round 1 (May 2017) participants were asked to 1) rate each definition as acceptable or unacceptable; 2) indicate a preferred definition or indicate that neither definition was appropriate; and 3) provide comment on the wording and content of proposed definitions. We calculated the proportion of participants who considered each definition acceptable or unacceptable. It was decided a priori that if a definition was preferred by $\geq 70\%$ of participants (n = 27) and was considered unacceptable by $< 30\%$, no further Delphi rounds would be required. If these criteria were not met, the lowest ranked definition would be removed and the retained definition would be modified in response to comments from the Delphi contributors. Feedback received from contributors was reviewed and considered by the core study team (P.H., N.C., J.S., M.F.). This review resulted in several modifications of flare candidate definition 2, which was assessed in round 2.

Round 2

The revised version of definition 2 was presented to the Delphi panel (August 2017). Participants who contributed to round 1 were invited to participate in round 2 (50 of 61 potential participants agreed). Round 2 participants were asked to indicate the degree to which they considered the modified definition to be acceptable using a scale from 1 (strongly disagree) to 10 (strongly agree). If they considered that the definition was unacceptable, a justification was requested. Two e-mail reminders were sent to maximize response rate. It was established a priori that the definition would be accepted and no further Delphi rounds would be conducted if it received a mean acceptability score of ≥ 7 . The mean score was calculated and feedback was considered by the core study group (P.H., N.C., J.S., M.F.).

Step 4: Testing Understanding of Definition With Individuals With LBP

Individuals were invited to participate through advertisements placed on social media, local community and health centers, word of mouth, and a contact list of participants from previous studies of LBP. Our intention was to include participants with diversity in their presentation to gain broad insight into the understanding of our definition. Eligible participants had to meet the following criteria: 1) ≥ 18 years of age, 2) ability to communicate in English, and 3) self-identification of current

or previous LBP. There was no exclusion for LBP duration or other coexisting pain and comorbidities. Recruitment was ongoing during the analysis and final numbers were decided by the principle of saturation (when no new information relevant to the study was being identified).⁵ Before the beginning of each consultation, the interviewer read the participant information sheet to each participant. All consultations were commenced after obtaining verbal consent for study participation and recording. Step 4 aimed to determine i) whether the final definition of a LBP flare was understandable to individuals with LBP, and ii) whether they would know how to act on this definition in relevant contexts. P.H. and J.S. designed three purpose-built scenarios (Table 1) to depict situations where an individual with LBP might be expected to recognize a flare as i) a reason to take action in response to a flare (eg, take medication); ii) a prompt to contact a researcher in a study of LBP flares to report their symptom status; and iii) a measure of outcome after a treatment. Participants were provided with the flare definition and 1 of the 3 scenarios (random allocation) during an audio-recorded telephone consultation by J.S. and N.C. J.S. is a female physiotherapist with 20 years of experience working with pain, a PhD in health psychology, and is experienced with qualitative research. N.C. is also a physiotherapist, has 6 years of experience working with persistent pain, and has received training in qualitative analysis. If participants could determine how to respond appropriately to the scenarios (Table 1) with the embedded flare description,

Table 1. Scenarios used in Step 4

Scenario 1

Imagine you are participating in university research that is investigating low back pain. You meet with the research team. They asked you a number of questions and take some measurements. Before you leave they ask you to contact them again if you have a *flare up* of your back pain. The researchers say: "A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to tolerate and generally impacts your usual activities and/or emotions."

Question:

Would you know when to contact the researchers again?

Scenario 2

Imagine you are at a consultation with your doctor discussing your low back pain. The doctor asks you to take a particular medication when you are experiencing a *flare*. She says: "A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to tolerate and generally impacts your usual activities and/or emotions."

Question:

Would you know when to take the medication?

Scenario 3

Imagine you are thinking about the success of a treatment for your low back pain. More specifically, you were thinking about whether back pain was better as a result of the treatment. Would you feel like you have improved if your low back pain flare-ups have reduced according to the following definition: "A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to tolerate and generally impacts your usual activities and/or emotions."?

Question:

Does a reduction of flare according to this definition mean you have improved?

the participant was deemed to have understood the definition. For instance, if participants answered "yes" to the question, "Would you know when to contact researchers again?", we considered the affirmative answer to be evidence that they understood the definition. Further confirmation was sought through follow-up questions including requests to paraphrase the flare definition, clarify whether they had experienced flares of their symptoms according to the definition, and discuss how they differentiated a flare from other fluctuations of their symptoms. The percentages of people who paraphrased the definition using different domains and experienced LBP flares according to the definition provided were calculated. Qualitative analysis was iterative using 4 stages. In stage 1, J.S. and N.C. wrote notes regarding whether the participants they interviewed seemed to understand the scenarios based on their responses to the 4 questions as outlined. These researchers also made notes of any other relevant responses from participants. In stage 2, notes were considered between the 2 researchers and any discrepancies discussed. In stage 3, results, including any discrepancies were discussed with a third researcher (who was not involved in the interview process). In stage 4, the overall results were shared with the core research team for input (N.C., M.F., J.S., P.H.).

Results

Step 1: Derivation of the LBP Flare Definition From the Consumer's Perspectives

The published results of a thematic analysis of an online survey confirmed that people who experience LBP consider flare to be a type of fluctuation which involves other domains in addition to pain.¹⁵ The core research team (P.H., N.C., J.S., M.F.) discussed how best to encapsulate i) the dimensions of flare beyond an increase in pain, ii) temporal features, and iii) other domains that would distinguish a flare from other fluctuations of symptoms. Emphasis was placed on making the definition simple using terminology that would be understandable to consumers, clinicians and researchers. Consultation with the expert consumer health writer (T.D.) highlighted that some terms (eg, function) would not be clear to consumers. The proposed definition was: "A flare is an increase in pain or other related symptoms that lasts from hours to weeks and is difficult to settle. You may also have mood changes and/or difficulty with your normal activity."

Step 2: Incorporation of Experts' Perspectives in the Preliminary LBP Flare Definition

The candidate flare definition was presented to the workshop attendees, who provided feedback in 5 main areas. Workshop participants' feedback included that:

- i) The phrase “increase in pain and other related symptoms” was considered imprecise. Terminology was simplified to “worsening of symptoms” with the intention to cover all potential symptoms associated with LBP rather than highlighting pain.
- ii) The term “symptoms” was considered too broad and specific symptoms should be listed (eg, area of symptoms, fatigue, etc). No change was made because such a list would make the definition too long for easy comprehension and would not cover all possible symptoms.
- iii) There was consensus that the definition should be clearer about consequences such as impact/changes in life. Statements such as “difficult to deal with,” “has an impact on your function and emotions,” and “it is difficult to settle and may be difficult to cope with” were considered.
- iv) The phrase “difficult to settle” was considered unclear. The alternative, “resolve,” was also considered inappropriate as it implies complete recovery. Based on this, “difficult to settle” was removed from 2 versions of the definition but kept in the other 2 to be further discussed.

P.H., N.C., J.S., and M.F. discussed feedback and rephrased the definition in 4 options, which were then refined to 2 candidate flare definitions with improved word clarity and readability (Table 2). The 2 candidate definitions were assessed in step 3.

Step 3: Delphi Process to Refine Definition and Reach a Consensus Expert Opinion

Round 1

Nineteen participants of the step 2 workshop, 19 members of the organizing committee of the International Forum for Back and Neck Pain Research in Primary Care, and 23 other individuals with expertise in flare in LBP or related conditions, or international reputation in research related to musculoskeletal pain were invited to participate in Step 3. Fifty of 61 (82%) invited experts agreed to participate. Twelve (24%) preferred definition 1 (“A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to improve and hard to cope with”), 31 (62%) favored definition 2 (“A flare-up is a worsening of your condition that lasts from hours to weeks that does not improve easily and may impact your usual activities and emotions”), and 7 (14%) did not accept either of the candidate flare definitions. Twenty-three participating experts (46%) considered definition 1 was unacceptable. Only eleven (22%) experts found definition 2 unacceptable. Because 78% participants found definition 2 acceptable and only 54% considered definition 1 acceptable, definition 1 was rejected. The rationale provided by participants for their choices were collated and the following issues were identified: i) use of “may” is redundant, ii) minimal symptom intensity and length should be specified, iii)

Table 2. LBP flare definition proposed at each step:

STEP	PROGRESSION OF THE DEFINITION
Step 1: Derivation of LBP flare definition from patient’s perspectives	A flare is an increase in pain or other related symptoms that lasts from hours to weeks and is difficult to settle. You may also have mood changes and/or difficulty with your normal activity.
Step 2: Incorporation of experts’ perspectives in preliminary LBP flare definition	Initial proposal: <ol style="list-style-type: none"> 1) A flare is a worsening of your condition that lasts from hours to weeks and is difficult to deal with. 2) A flare is a worsening of your condition that lasts from hours to weeks and has an impact on your function and emotions. 3) A flare is a worsening of your condition that lasts from hours to weeks. It is difficult to settle and has an impact on your function and emotions. 4) A flare is a worsening of your condition that lasts from hours to weeks. It is difficult to settle and may be difficult to cope with. Refined to reduce to a single sentence and refine wording based on consultation with consumer writer: <ol style="list-style-type: none"> 1) A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to improve and hard to cope with. 2) A flare-up is a worsening of your condition that lasts from hours to weeks that does not improve easily and may impact your usual activities and emotions.
Step 3: Delphi process to refine definition and reach consensus expert opinion	Round 1: <ol style="list-style-type: none"> 1) A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to improve and hard to cope with. 2) A flare-up is a worsening of your condition that lasts from hours to weeks that does not improve easily and may impact your usual activities and emotions. Round 2: A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to tolerate and generally impacts your usual activity and/or emotions.
Step 4: Testing understanding of definition with individuals with LBP	No change from step 3.

"difficult to improve" is too narrow, and iv) "impact on activities and emotions" may not apply to all individuals all of the time. After considering this feedback, the core research group undertook the following modifications, the word "may" was removed, a minimal length of "a day" was added, "difficult to improve" was replaced by "difficult to tolerate," and the word "generally" was added to emphasize that the impact on activities and emotions is not always present (Table 2). No changes were made regarding minimal symptom intensity because this directly contrasted the outcome of step 1.²² The modified version of definition 2 was submitted to a second Delphi round.

Round 2

Of the 50 experts who participated in round 1, there were 44 (88%) who contributed to round 2. The average rating of acceptability for the proposed definition was 8.1 out of 10.0 and 40 participants (91%) provided a rating equal or greater than the a priori established cutoff to accept the definition of 7 out of 10. Only 1 participant who responded negatively to the first round did not respond to the second round. Several participants from round 2 highlighted that flares can last for hours. Because this also concurred with some views from step 1,²² "a day" was replaced by "hours." The final proposed definition for LBP flare is presented in Table 2.

Step 4: Testing Understanding of the Definition With Individuals With LBP

Sixteen consumers participated in the telephone consultations. Most lived in Australia ($n = 15$); 1 participant lived in the United States. The mean age was 43.5 years old (range, 21–72 years). More than one-half of participants were male ($n = 9$). Consistent with our objective, our sample had a broad distribution of features and trajectories. The average duration of a symptom-free period varied from hours to 1 year. The mean current pain level was 2.0 (range, 0–8) and the mean of maximum intensity of LBP over the past 3 months was 5.7 (range, 0–10). Other key characteristics were: participants had first experienced LBP an average of 16 years ago (range, 1–55 years); 69% reported current symptoms; the 5 participants with no current pain included 1 who had a symptom-free period of 1 week, 1 for 2 months, and 3 participants with no pain for >2 months; 5 participants experienced leg pain (sciatica) and 1 participant reported a previous vertebral fracture. Three participants had self-reported arthritis and only 1 had ankylosing spondylitis. No participants had fibromyalgia, rheumatoid arthritis (RA), or had undergone surgery.

All participants were able to understand the LBP flare definition as indicated by their response to the scenario they were given. Fifteen of the 16 participants (94%) stated that they would know how to act in the given scenario, for example: "what you are looking for is the difference between normal and when it gets worse, so yes" (P10). Another participant said that he would know how to act based on the definition provided as "the flare-ups

are quite debilitating where I can't stand all the way up and any sort of movement or walking activity can be quite painful. It's quite a specific feeling" (P11).

Further evidence that our definition of flare was acceptable and understandable to the participants was the fact that all were able to paraphrase the definition, although the level of detail varied between participants. Most participants (87.5%) included most of the definition domains, suggesting that they understood the aspects of the definition that extended beyond simply pain. For instance, P10 "It's bad enough that interferes with your life and emotions. When you go and 'I can't do that because my back is sore,'" and P1 said that a flare would be "A worsening of the pain that lasts between hours and weeks—so longer than just a transitory thing—that is bad enough that is interfering with living your life or emotions." Only 2 participants (12.5%) rephrased focusing only on 1 or 2 aspects highlighted on the definition provided: one stated that, "A flare is when it becomes worse" (P3), and the other considered flare as "The severity of my back pain affecting my day-to-day activities" (P6). This finding aligned with our expectation that not all people who have LBP flares will experience all aspects included within the definition, but that it will be broad enough for most people to relate to.

Almost all participants (15 of the 16) reported previous LBP flares and could relate these flare experiences to the definition provided. Consistent with our definition, when asked about how they would distinguish flares from other fluctuations most highlighted other dimensions in addition to pain. Some participants related flares to the necessity to rest: "Yeah is when it gets to that level where I just feel really strong pain and I have to actually lay down to feel a bit better, that's when I know I have a flare-up" (P4). Others stated that flares were intolerable and with broader impact than other fluctuations: "So when it starts to become intolerable I would say...when it's going to impact my daily life, when it's going to impede on my tasks..." (P15). Another participant highlighted that flares usually go beyond a certain level of variation: "Yeah I think that, in my head anyway, there is a difference between normal, like you know is a bit sore today, to—this is really bothering me! That's the thing you know, it's out of the normal range."

Discussion

This study produced a definition of LBP flare that is based on perspectives of individuals with LBP, represents a consensus opinion of experts, and is understandable to individuals with LBP in a range of relevant contexts. The final agreed definition is: "A flare-up is a worsening of your condition that lasts from hours to weeks that is difficult to tolerate and generally impacts your usual activities and/or emotions."

Contextualizing the Findings

The new proposed definition of a LBP flare differs from the definition proposed by Von Korff²⁹ in several important aspects. First, Von Korff's definition of flare

only applied to chronic or recurrent LBP. This contrasts the intention of the proposed definition to apply to LBP irrespective of whether it is acute, chronic, recurrent, or resolved. Second, Von Korff focused on pain that lasts for ≤ 1 week and does not consider fluctuations of longer duration. The proposed definition is better aligned with opinions of individuals with LBP²² and contemporary understanding of LBP course,^{6,14,27} taking into consideration symptoms that last for hours to weeks. Third, pain is the only domain considered in Von Korff's flare definition. Consistent with qualitative research investigating individual's perspectives on LBP flares,²² the new definition considers other domains, such as impact on function and emotions, but does not require all those features to be present simultaneously to characterize a flare. Taking into consideration the multidimensional nature of symptoms considered in flare, we did not include a minimum threshold of change in pain to describe a flare. This decision was based on results of the qualitative work that showed people who experience LBP do not consider pain sufficient to characterize a flare.²² It was an objective of our process to provide a definition of LBP flare that could be applied to a diverse group with LBP. This was reinforced by our process, which included experts from multiple disciplines, encouraged experts to consider LBP broadly (and not consider a narrow group), and included a group of individuals with LBP that had a diverse array of features and trajectories.

It is important to consider how the proposed definition differs from other types of LBP fluctuations. Other frequently discussed types of fluctuation are *episode*, defined as "a period of pain in the lower back lasting for more than 24 hours, preceded and followed by a period of at least one month without low back pain"¹²; and *recurrence* of an episode, defined as "A return of LBP lasting at least 24hrs with a pain intensity of >2 on an 11-point NRS (>20 mm on a 100mm VAS [visual analog scale]) following a period of at least 30 days pain-free."²⁴ The main distinction from the proposed flare definition is that *episodes* and *recurrences* are specific types of fluctuation preceded by a period without pain, whereas a flare can be any increase in symptoms either superimposed on ongoing symptoms or a pain-free state. As such, an episode or recurrence might be considered a specific type of flare. An important consideration is that many individuals with LBP consider they continue to have the condition of LBP, even when they are symptom free,³⁰ which is congruent with the proposed flare definition, but might complicate the interpretation of an episode or recurrence.

Multidimensional flare definitions are also described for other musculoskeletal conditions.⁹ For instance, in RA, flares have been considered to represent "a cluster of symptoms of sufficient duration and intensity to require (re)initiation, change, or increase in therapy."⁴ The OMERACT RA group that developed this definition considered a broader range of symptoms in addition to pain and did not establish a minimal threshold of symptom intensity, similar to the proposed definition of a LBP flare. The multidimensionality of RA flare has

subsequently underpinned development of a tool to quantify changes in multiple domains. Research in gout and psoriatic arthritis have followed a similar trajectory with current work toward an instrument to identify flares based on multiple domains.^{16,20} In psoriatic arthritis, flares have been defined as "an overwhelming collection of physical, psychological and emotional symptoms,"¹⁹ which considers the physical flare experience to be linked to psychological and emotional symptoms. This definition differs slightly from the proposed definition of a LBP flare, because the emotional changes are not necessarily present in the latter. It is important to note that the mechanisms and nature of flares in RA, gout, and psoriatic arthritis are likely to differ from those of LBP. It is for this reason that it has been necessary to undertake this comprehensive process to develop a definition that is specific to LBP. This process has highlighted some similarities, but also some differences, as highlighted.

Study Strengths

The definition of a LBP flare that was developed in this study used a multistep process designed to include participation of individuals with LBP and expert consensus. No previous community input has been obtained to facilitate an understanding of LBP flares. As expected for a Delphi approach, not all expert opinions could be included in the final output, and the final definition was the product of agreement by the majority. Some opinions are not reflected in the final definition. For example, some experts did not consider that a worsening of symptoms that lasts only a few hours was sufficient to be considered a flare. Further, some experts did not consider emotional changes as an important feature of LBP flares, whereas this was emphasized by some people who experience LBP flares in the previous qualitative study.²²

Study Limitations

Although we made efforts to consider a broad range of experts' perspectives, it is possible that we have excluded valuable opinions of experts who were not invited to participate or did not meet our inclusion criteria for step 3. Another potential limitation of the current study is that individuals with LBP who participated in step 4 had first experienced LBP an average of 16 years ago (range, 1–55). Thus, our sample was biased toward those with long-term recurring, persistent, or chronic symptoms. The long-term nature of their LBP would be likely to influence their interpretation and understanding of the LBP flare definition proposed. This factor may impact the transferability of our findings when considering people who experience flares within a first episode of acute symptoms. Of note, recent work argues that many individuals consider they have LBP, even when they are in remission.³⁰ The 5 individuals in step 4 who had no current symptoms indicated that they would know how to act in the scenarios we presented,

but future work could further test the usefulness of the definition for individuals with occasional LBP episodes.

The proposed definition of a LBP flare was tested in hypothetical scenarios rather than in real-life contexts. This might decrease the external validity of our findings on the community understanding of this definition. It is important to consider that language and culture might affect the use of the word *flare* and its definition, even in countries where English is the native language. An unanswered question pertaining to the current definition of a LBP flare and work that has been done for other musculoskeletal conditions is whether a definition alone is sufficient to characterize such LBP fluctuations or whether tools that quantify changes in multiple different domains are required. A comparison of these approaches would be valuable to consider in future research.

Another important consideration is that, because flare is expressed in different ways by different people, the definition required scope to encompass variable presentation to capture more flares. No quantitative value could be placed on specific aspects (eg, minimum increase in pain). There was also no restriction or mention of which symptom was worsened (eg, back pain, leg pain). The compromise is that this may make the proposed definition less precise than a definition with quantitative limits. This consideration reflects the challenge to represent the views of patients and clinicians with the risk that the definition is neither optimized to reflect consumer view nor provide an objective measure for research. Although we argue that the outcomes of the consensus process with experts and patient validation suggest that we achieved both objectives, we acknowledge that there are some potential limitations and further work should be undertaken to assess features such as reliability. Further, additional steps could be considered, such as the development of a complementary assessment scale that evaluates multiple separate domains to characterize the nature of the flare (as

has been undertaken in RA⁴), once the presence of a flare has been identified according to the definition developed here.

Conclusions

This consensus definition takes into account that pain increase alone is unlikely to be sufficient as a definition or marker of LBP flares. Our results operationalize a multidimensional definition of a flare that we have shown is understood by individuals who have experienced LBP if used in clinical and research contexts. The definition is based on the premise that flare measurements (in future LBP studies) should consider a broad community understanding of the term and aims to differentiate between types of fluctuation across different LBP trajectories. This definition will have usefulness in epidemiologic studies and have clinical implications with respect to measuring treatment efficacy.

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Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jpain.2019.03.009>.

References

1. Axén I, Leboeuf-Yde C: Trajectories of low back pain. *Best Pract Res Clin Rheumatol* 27:601-612, 2013
2. Buchbinder R, van Tulder M, Öberg B, Costa LM, Woolf A, Schoene M, Croft P, Buchbinder R, Hartvigsen J, Cherkin D, Foster NE, Maher CG, Underwood M, van Tulder M, Anema JR, Chou R, Cohen SP, Menezes Costa L, Croft P, Ferreira M, Ferreira PH, Fritz JM, Genevay S, Gross DP, Hancock MJ, Hoy D, Karppinen J, Koes BW, Kongsted A, Louw Q, Öberg B, Peul WC, Pransky G, Schoene M, Sieper J, Smeets RJ, Turner JA, Woolf A: Low back pain: A call for action. *Lancet* 391:2384-2388, 2018
3. Bunzli S, Watkins R, Smith A, Schütze R, P OS: Lives on hold: A qualitative synthesis exploring the experience of chronic low-back pain. *Clin J Pain* 29:907-916, 2013
4. Bykerk VP, Bingham CO, Choy EH, Lin D, Alten R, Christensen R, Furst DE, Hewlett S, Leong A, March L, Woodworth T, Boire G, Haraoui B, Hitchon C, Jamal S, Keystone EC, Pope J, Tin D, Thorne JC, Bartlett SJ: Identifying flares in rheumatoid arthritis: Reliability and construct validation of the OMERACT RA Flare Core Domain Set. *RMD Open* 2, 2016
5. Caelli K, Ray L, Mill J: 'Clear as mud': Toward greater clarity in generic qualitative research. *Int J Qual Methods* 2:1-13, 2003
6. Chen Y, Campbell P, Strauss VY, Foster NE, Jordan KP, Dunn KM: Trajectories and predictors of the long-term course of low back pain: Cohort study with 5-year follow-up. *Pain* 159:252-260, 2018
7. Global Burden of Disease Study 2013 Collaborators: Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: A systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 386:743-800, 2015
8. Coole C, Drummond A, Watson PJ, Radford K: What concerns workers with low back pain? Findings of a qualitative study of patients referred for rehabilitation. *J Occup Rehabil* 20:472-480, 2010

9. Costa N, Ferreira ML, Cross M, Makovey J, Hodges PW: How is symptom flare defined in musculoskeletal conditions: A systematic review. *Semin Arthritis Rheum* 48:302-317, 2018
10. Croft PR, Macfarlane GJ, Papageorgiou AC, Thomas E, Silman AJ: Outcome of low back pain in general practice: A prospective study. *BMJ* 316:1356, 1998
11. Cross M, Dubouis L, Mangin M, Hunter DJ, March L, Hawker G, Guillemin F: Defining flare in osteoarthritis of the hip and knee: A systematic literature review — OMER-ACT Virtual Special Interest Group. *J Rheumatol* 44:1920-1927, 2017
12. de Vet HCW, Heymans MW, Dunn KM, Pope DP, van der Beek AJ, Macfarlane GJ, Bouter LM, Croft PR: Episodes of low back pain: A proposal for uniform definitions to be used in research. *Spine* 27:2409-2416, 2002
13. Diamond IR, Grant RC, Feldman BM, Pencharz PB, Ling SC, Moore AM, Wales PW: Defining consensus: A systematic review recommends methodologic criteria for reporting of Delphi studies. *J Clin Epidemiol* 67:401-409, 2014
14. Dunn KM, Campbell P, Jordan KP: Long-term trajectories of back pain: Cohort study with 7-year follow-up. *BMJ Open* 3, 2013
15. Dunn KM, Hestbaek L, Cassidy JD: Low back pain across the life course. *Best Pract Res Clin Rheumatol* 27:591-600, 2013
16. Gaffo AL, Schumacher HR, Saag KG, Taylor WJ, Dinnella J, Outman R, Chen L, Dalbeth N, Sivera F, Vázquez-Mellado J, Chou CT, Zeng X, Perez-Ruiz F, Kowalski SC, Goldenstein-Schainberg C, Chan L, Bardin T, Singh JA: Developing a provisional definition of flare in patients with established gout. *Arthritis Rheum* 64:1508-1517, 2012
17. Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, Hoy D, Karppinen J, Pransky G, Sieper J, Smeets RJ, Underwood M, Buchbinder R, Hartvigsen J, Cherkin D, Foster NE, Maher CG, Underwood M, van Tulder M, Anema JR, Chou R, Cohen SP, Menezes Costa L, Croft P, Ferreira M, Ferreira PH, Fritz JM, Genevay S, Gross DP, Hancock MJ, Hoy D, Karppinen J, Koes BW, Kongsted A, Louw Q, Öberg B, Peul WC, Pransky G, Schoene M, Sieper J, Smeets RJ, Turner JA, Woolf A: What low back pain is why we need to pay attention. *Lancet* 391:2356-2367, 2018
18. Kongsted A, Kent P, Axen I, Downie AS, Dunn KM: What have we learned from ten years of trajectory research in low back pain? *BMC Musculoskelet Disord* 17:220, 2016
19. Moverley AR, Vinall-Collier KA, Helliwell PS: It's not just the joints, it's the whole thing: Qualitative analysis of patients' experience of flare in psoriatic arthritis. *Rheumatology* 54:1448-1453, 2015
20. Moverley AR, Waxman R, de Wit M, Parkinson A, Campbell W, Brooke M, Gossec L, Helliwell PS: Development of a flare instrument for use in psoriatic disease: A report from the 2015 GRAPPA Annual Meeting. *J Rheumatol* 43:974-978, 2016
21. Murphy SL, Lyden AK, Kratz AL, Fritz H, Williams DA, Clauw DJ, Gammaitoni AR, Phillips K: Characterizing pain flares from the perspective of individuals with symptomatic knee osteoarthritis. *Arthritis Care Res* 67:1103-1111, 2015
22. Setchell J, Costa N, Ferreira M, Makovey J, Nielsen M, Hodges Paul W: What constitutes back pain flare? A cross sectional survey of individuals with low back pain. *Scand J Pain*, 2017
23. Stanton TR, Latimer J, Maher CG, Hancock M: Definitions of recurrence of an episode of low back pain: A systematic review. *Spine* 34:E316-E322, 2009
24. Stanton TR, Latimer J, Maher CG, Hancock MJ: A modified Delphi approach to standardize low back pain recurrence terminology. *Eur Spine J* 20:744-752, 2011
25. Suri P, Rainville J, Fitzmaurice GM, Katz JN, Jamison RN, Martha J, Hartigan C, Limke J, Jouve C, Hunter DJ: Acute low back pain is marked by variability: An internet-based pilot study. *BMC Musculoskelet Disord* 12, 2011. 220-220
26. Suri P, Saunders KW, Von Korff M: Prevalence and characteristics of flare-ups of chronic nonspecific back pain in primary care: A telephone survey. *Clin J Pain* 28:573-580, 2012
27. Tamcan O, Mannion AF, Eisenring C, Horisberger B, Elfering A, Müller U: The course of chronic and recurrent low back pain in the general population. *Pain* 150:451-457, 2010
28. Vincent A, Whipple MO, Rhudy LM: Fibromyalgia flares: A qualitative analysis. *Pain Med* 17:463-468, 2016
29. Von Korff M: Studying the natural history of back pain. *Spine* 19:2041S-2046S, 1994
30. Young AE, Wasiak R, Phillips L, Gross DP: Workers' perspectives on low back pain recurrence: "it comes and goes and comes and goes, but it's always there. *Pain* 152:204-211, 2011